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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,904

Applicant(s)

GARNER ET AL.

Examiner

Marjorie A. Moran

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,9-42,44-53,56-213 is/are pending in the application.
- 4a) Of the above claim(s) 11,13-21,23-36,58-202 and 205-213 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9,10,12,22,37-42,44-53,56,57,203 and 204 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 11, 13-21, 23-36, and 58-202, and 205-213 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in a paper filed 11/3/03. Applicant is assured that upon a finding of allowability of a generic claim, claims directed to nonelected species will be rejoined and examined.

An action on the merits of elected claims 1-3, 5-7, 9-10, 12, 22, and 37-42, 44-53, 56-57, 203 and 204, as they read on the elected species, follows.

All rejections and objections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-7, 9-10, 12, 22, and 37-42, 44-53, 56-57, 203 and 204 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Calculating a variation frequency within a group of bases, as recited in amended claims 1 and 203, is new matter. Comparing a nucleic acid sequence with a matrix one or groups at a time, as recited in amended claims 1 and 203, is new matter. Identifying the location of a variation in one or more bases in a sequence where SNPs will likely occur, or a location likely to cause a variation, as recited in amended claims 1 and 204, is new matter. Comparing a sequence three or more bases at a time with a matrix, as recited in amended claim 57, is new matter.

In the response filed 1/19/06, applicant points to paragraphs 65-67 for support for all amendments. These paragraphs provide support for comparing *codons* to a predictive matrix in order to identify or predict variations which will result in a phenotypic mutation or disease. The originally filed specification, in para. 58, discloses identifying locations in a GENOME which may be prone to variation, thus resulting in mutation/disease. All predictive matrices and comparison disclosed in the originally filed specification are for *codons*, or triplets, of nucleic acids. Nowhere does the specification disclose comparison or matrices of "groups" of nucleic acids wherein a group comprises any number other than three (i.e. a codon or triplet). The originally filed claims (e.g. original claim 1) disclosed comparison of "one or more bases," which is not supportive of the now claimed "groups," which are different in scope. Nowhere do the originally filed specification or claims provide support for the new range of "three or more" bases now recited in amended claim 57.

Original claim 1 recited predicting one or more SNPs based on a variation predictiveness matrix, but the original claims did not recite identifying a the *location* of a

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variation where a SNP is likely to occur nor identifying a location *likely to cause* a variation. It is unclear what is actually being claimed (see below). However, nowhere does the originally filed specification disclose identifying a location (position) *of a variation* in a nucleic acid sequence or genome, etc. where a SNP is likely to occur. It is recognized that this new matter may be due to a typographical error in the amendment. It is noted that the originally filed specification does provide support for a method of predicting the location (in a nucleic acid sequence) where a SNP is likely to occur. Also, a method/code for identifying a variation (e.g. SNP) likely to cause a phenotypic mutation or disease is also supported, but NOT a method wherein a location of a variation likely to *cause* a SNP is identified.

As the original claims and specification fail to provide support for the new limitations recited in the amended claims, the claims recite new matter and are rejected.

Claims 1-3, 5-7, 9-10, 12, 22, and 37-42, 44-53, 56-57, 203 and 204 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples;

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the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled because neither the prior art nor specification teaches how to identify the locations of variations where SNPs are likely to occur or that will likely cause a variation in one or more bases of a nucleic acid sequence.

It is noted that a single nucleotide polymorphism (SNP), by definition, IS a variation in a single base, therefore it would be redundant or impossible, depending on one's interpretation of the claims, to identify a SNP that "likely" causes a variation in a base of a nucleic acid sequence. Where the method is interpreted as predicting a SNP, then it is inherently a method of predicting the variation of one or more bases in a nucleic acid sequence, and the final "step" of claims 1 and 203 is nonsensical. If the method is actually intended to be one of identifying variations that predict/cause variations (SNPs that cause SNPs? mutations that cause SNPs?), then the method is not enabled as one skilled in the art would not know how to predict a SNP or other single nucleotide variation "caused by" or "based on" a location of a sequence "variation". Neither the prior art nor the instant specification teach how to predict a base variation "caused by" or "based on" a variation or knowledge of the location of a variation in a sequence. If the method is intended to be one of predicting the likelihood of a SNP occurring at any given (or selected) position in a nucleic acid sequence, then it is noted that the claims do not actually recite this limitation.

Applicant's arguments do not address the points set forth above. Applicant is commended for attempting to overcome the enablement rejections set forth in the

previous office action, and is encouraged to contact the examiner if further questions arise with regard to the instant rejections.

For these reasons, those previously set forth and set forth above, the examiner maintains that the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-7, 9-10, 12, 22, and 37-42, 44-53, 56-57, 203 and 204 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claims 1 and 203 recite a step/code for identifying the location of variation in one or more bases of a nucleic acid sequence where SNPs will likely occur. This is nonsensical. A SNP IS a "variation" in a single base, by definition. If a larger polymorphism or mutation occurs (i.e. variation of more than one base), then the "variation" can not predict a SNP. It is therefore it is unclear whether the recited "variation" is intended to be something different than a SNP or other polymorphism. If applicant actually intends to predict THE location of a SNP, then applicant is encouraged to amend the claims to clearly reflect the intended limitation.

Claim 57 recites the limitation "the step of comparing ...three or more bases at a time" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Parent claim 1 recites a step of comparing a sequence one or more groups at a time,

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but does not recite a step of comparing three or more bases at a time, and thus does not provide antecedent basis for the step of claim 57.

Amended claim 204 recite a code segment for identifying the location of variation in one or more bases of a nucleic acid sequence that will likely cause a variation. It is not clear in what way a LOCATION is intended to cause a mutation or SNP; i.e. variation in a codon. A mutation, polymorphism, etc. is generally defined BY the location where it occurs, therefore a limitation to predict a location which CAUSES a variation is nonsensical. If applicant intends either the term "location" or "variation" to mean something different than that generally accepted by those skilled in the art, then applicant is reminded that such definitions must be clearly set forth in the instant specification.

Applicant is reminded that any amendments, definitions, etc. must be fully supported and enabled by the originally filed disclosure.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
4/13/06